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Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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January 16, 2020

Ms. Brenda Destro
Deputy Assistant Secretary
Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Deputy Assistant Secretary Destro:

We write to request information about the actions that the U.S. Department of Health and Human Services (HHS) has taken to cultivate innovation in Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/ADRD or Alzheimer's) research, as well as barriers that stand in the way of discovering treatments or cures for AD/ADRD, and the ways in which Congress can assist in overcoming such barriers. Despite sustained federal involvement, Alzheimer's Disease remains the only top 10 cause of death in the United States that cannot be cured, treated, or slowed.[1]

Alzheimer's research and the search for a cure or treatment is, and has been, a priority of HHS for many years. Several HHS agencies, including the National Institute on Aging (NIA) of the National Institutes of Health, (NIH), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), and the Centers for Disease Control and Prevention are responsible for ensuring that various aspects of Alzheimer's research and prevention continue to progress.

ASPE plays an important role in the continued implementation of the National Alzheimer's Project Act (NAPA) by updating and tracking the progress of the National Plan to Address Alzheimer's Disease (the National Plan),[2] updating Alzheimer's research priorities and milestones, identifying key indicators of progress within Alzheimer's research, convening research summits, and working with global partners to enhance collaboration on Alzheimer's

[1] Alzheimer's & Dementia 14 (2018) 367 – 439, Alzheimer's Association Report: 2018 Alzheimer's disease facts and figures at 383, *available at* https://www.alzheimersanddementia.com/article/S1552-5260(18)30041-4/pdf.
[2] Office of The Assistant Secretary for Planning and Evaluation, *National Plans to Address Alzheimer's Disease* (Oct. 24, 2019), *available at* https://aspe.hhs.gov/national-plans-address-alzheimers-disease.

research. Because of ASPE's important role, we are interested in understanding more about how ASPE has coordinated research priorities, efforts, and planning to more effectively implement NAPA given its role as HHS' principal advisor on policy development, and its responsibility for major activities in legislation development, policy coordination and research, strategic planning, evaluation, and economic analysis.

Congress has been active in promoting a cure or treatment for Alzheimer's, passing multiple pieces of legislation in the last decade. In 2011, Congress passed, and President Obama signed into law, the National Alzheimer's Project Act (NAPA). Through NAPA, Congress charged HHS with establishing the National Alzheimer's Project, and included six objectives regarding diagnosis, treatment, and research for AD/ADRD.[3] In pursuit of these six objectives, HHS promulgated the National Plan, which established five goals and acted as a road map for both the federal government and the research community.[4] In 2014, the Alzheimer's Accountability Act was enacted as part of the Fiscal Year (FY) 2015 omnibus appropriations bill.[5] The Alzheimer's Accountability Act requires the scientists at NIH to submit an annual Alzheimer's research budget proposal directly to Congress—known as the Alzheimer's Bypass Budget—specifying the resources that scientists need to reach the National Alzheimer's Plan goal of preventing and effectively treating AD/ADRD by 2025. In addition, in 2018, the Building Our Largest Dementia (BOLD) Infrastructure for Alzheimer's Act was signed into law.[6] In an effort to bolster AD/ADRD progress, the BOLD Act further authorized the expansion of activities related to combating AD/ADRD.

Congress has also demonstrated a commitment to AD/ADRD research by appropriating additional funding annually. For FY 2018, Congress approved an additional $414 million for Alzheimer's research, bringing the total funding to $1.828 billion.[7] For FY 2019, Congress directed NIH to reserve $2.34 billion, an increase of $425 million from FY 2018.[8] Despite legislative action by Congress and increases in research funding, a cure or effective treatment for AD/ADRD remains out of reach.

There are promising developments, however. On October 22, 2019, Biogen announced that it planned to move forward in seeking regulatory approval from the U.S. Food and Drug

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[3] The six objectives are: 1) create and maintain a plan to overcome AD/ADRD; 2) coordinate AD/ADRD research across federal agencies; 3) accelerate the development of treatment; 4) improve early diagnosis; 5) decrease racial and ethnic disparities; and 6) coordinate international bodies. National Alzheimer's Project Act, Public Law No: 111-375 (Jan. 4, 2011), *available at* https://www.congress.gov/bill/111th-congress/senate-bill/3036.

[4] The five goals consisted of: 1) prevent and effectively treat AD/ADRD by 2025; 2) optimize care, quality, and efficiency; 3) expand support for people with AD/ADRD and their families; 4) enhance public awareness and engagement; and 5) track progress and drive improvement. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, National Plan to Address Alzheimer's Disease (Dec. 3, 2018), *available at* https://aspe.hhs.gov/national-plans-address-alzheimers-disease.

[5] Consolidated and Further Continuing Appropriations Act, 2015, Public Law No. 113-235 (Dec. 16, 2014), *available at* https://www.congress.gov/113/plaws/publ235/PLAW-113publ235.pdf.

[6] BOLD Infrastructure for Alzheimer's Act, Public Law No: 115-406 (Dec. 31, 2018), *available at* https://www.congress.gov/bill/115th-congress/senate-bill/2076.

[7] Congressional Record (Mar. 22, 2018), vol. 164, no.50—Book III, H2701.

[8] H. Rept. 115-952, p. 529.

Administration (FDA) of an investigational treatment for early Alzheimer's disease called aducanumab.[9] If approved by the FDA, this drug "would become the first therapy to reduce the clinical decline of Alzheimer's disease."[10] While promising, the drug has not been approved by the FDA to date; moreover, according to experts, an effective treatment for AD/ADRD will likely include several therapies.[11] Additionally, a recent paper published by researchers notes that a rare genetic mutation may have helped to delay Alzheimer's disease for a woman who was at risk for early onset of Alzheimer's disease.[12] This finding shifts the focus from the amyloid protein to the tau protein, and could inform and lead to new approaches to the treatment of Alzheimer's disease. These are just two examples of potential breakthroughs in the search for treatments and a cure for Alzheimer's disease, but additional research is needed.

Finding a cure or effective treatment for AD/ADRD will continue to require an all-hands-on-deck approach. ASPE plays an integral role in the continued implementation of NAPA, by tracking progress and updating research priorities and milestones. We request that written answers to the following questions be provided by January 30, 2020. We request you also provide a briefing to staff.

1. Is research on track to meet the primary goal of effectively treating and preventing AD/ADRD by 2025?

    a. If not, what factors does ASPE think stand in the way of achieving this goal?

    b. If not, what is the updated date to achieve the goal?

2. What is ASPE doing to ensure the National Plan to Address Alzheimer's Disease is effectively implemented, and the 2025 deadline is met?

    a. What resources and authorities does ASPE utilize available to implement the National Plan? Are these resources and authorities sufficient? If not, what additional resources or authorities are needed?

3. What has ASPE done to address the need for recruitment of diverse participation in AD/ADRD research studies to include representation from various socioeconomic, ethnic, and racial groups who may be affected differently?

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[9] Biogen, Biogen Plans Regulatory Filing for Aducanumab in Alzheimer's Disease Based on New Analysis of Larger Dataset from Phase 3 Studies (Oct. 22, 2019), *available at* http://investors.biogen.com/news-releases/news-release-details/biogen-plans-regulatory-filing-aducanumab-alzheimers-disease.

[10] *Id.*

[11] Tara Bahrampour, *In surprise turnaround, new analysis finds an Alzheimer's treatment may work*, WASH. POST (Oct. 22, 2019), *available at* https://www.washingtonpost.com/local/social-issues/in-surprise-turnaround-new-analysis-finds-an-alzheimers-treatment-may-work/2019/10/22/cb274fd8-f4e6-11e9-ad8b-85e2aa00b5ce_story.html.

[12] Linda Carroll, *Rare genetic finding may help in search for Alzheimer's therapies*, REUTERS (Nov. 4, 2019), *available at* https://www.reuters.com/article/us-health-alzheimers-genetics-idUSKBN1XE216.

4. What recommendations has ASPE made to other federal agencies involved in funding, regulating, guiding, or using research outcomes, to elevate AD/ADRD research study participation to a national priority?

5. Given that participation is critical for research success, are public service announcements or participation incentives being considered to promote the importance of participation in AD/ADRD research for the benefit of individuals, families, and society as a whole? Why or why not?

Thank you for your attention to this request. Should you have any questions, and to schedule the requested briefing, please contact Brittany Havens or Diane Cutler of the Republican Committee staff at (202) 225-3641.

Sincerely,

Greg Walden
Republican Leader

Brett Guthrie
Republican Leader
Subcommittee on Oversight
and Investigations

Michael C. Burgess, M.D.
Republican Leader
Subcommittee on Health